

Election/Restrictions

Applicant's election with traverse of group I in the reply filed on 9/23/09 is acknowledged. The traversal is on the ground(s) that the restriction requirement is moot in light of the 9/23/09 amendment. This is persuasive and in light of these amendments, the 7/17/09 restriction requirement will be withdrawn and all of the pending claims 16-36 will be considered

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The original disclosure fails to explicitly teach the indicator chamber being external to the reaction chamber. The Office has considered the specification and figures. Figure 1 and the associated description on page 5 are exemplary of the teachings of the instant invention. Specifically, the device has a **single** cup shaped element(1.1,1.6) that is covered by a **single** film(1.2). Within the formed cavity there is reaction chamber(1.5) and adjacent indicator chamber(2.0). The Office does not believe this supports the instant claim language of the reaction chamber external to the

Art Unit: 1797

indicator chamber. The specification teaches both chambers are between the same **single** cup shaped element and the same **single** film. It is not clear how these two chamber are external from each other when they are formed by the same element and film. A more accurate description might be that the two chambers are adjacent to each other. If the language "adjacent" were used instead "external", the 35 USC 112 1st paragraph rejection would be overcome. However, the Office believes the language "adjacent" may not define over Steinbrink under 35 USC 102(b).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinbrink (USP 4,078,892).

Steinbrink teach a kit for the determination of bilirubin in blood. Column 2 lines 6+ teach the kit(10) comprises flexible walled, hermetically sealed reagent containers(14) that are packaged in a kit so that elements are conveniently available when needed. Hub(34) on the containers(14) is pierced by pipette(28) and permits transfer of the sample into the container(14). The hub(34) has also been read on the claimed "break away tip" and "adhesive film covering said inlet." Column 4 lines 43-51 teach the containers(14) have flexible walls(18) and are constructed from plastic materials, such as polyethylene or polypropylene. Further, capsule(20) contain reagent solution(22) and is within container(14). Figure 1 shows there are a series of contains to make colorimetric comparison and has been read on the claimed "information-

Art Unit: 1797

carrying medium ... ". The Office has read the claimed "*reaction chamber*" on the taught **container(14)**; the claimed "*inlet*" on the taught **hub(34)** and the claimed "*indicator chamber*" on the taught **capsule(20)**.

Steinbrink teaches the indicator chamber is within the reaction chamber and is silent to the claimed indicator chamber "external" to the reaction chamber.

MPEP 2144.04(V) characterizes *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) as teaching "the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice." The Office understands this decision as teaching the choice of making a device from multiple components or as an integral device would have been "merely a matter of obvious engineering choice" and interchangeable obvious variations.

Steinbrink teaches the "reaction chamber" and the "indicator chamber" are integral. In the absence of a showing of unexpected results, one having ordinary skill in the art would have expected the identical results of fluid handling between the indicator chamber and the reaction chamber if either the two chambers were integral or one chamber is "external" from the other. It would have been within the skill of the art to modify Steinbrink to make the indicator chamber "external" or separate from the reaction chamber, to achieve the expected results of fluid handling, as "merely a matter of obvious engineering choice."

Steinbrink are silent to the claimed litmus test strip of claim 20, the indicator or reaction in the form of a tablet of claim 27 and the at least two reaction chambers and/or two indicator chambers of claims 34 and 36.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The choice of an indicator is a result effective variable having the well known and expected results of detecting the analyte of interest. Also, the physical state of an indicator or reaction is a result effective variable providing the well known and expected results of indication. Finally, the number of reaction chambers and/or indicator chambers is a result effective variable based upon the scale of analysis desired.

Litmus test strips are notoriously well known in the art for testing the pH of a solution and is advantageous because it is inexpensive and widely available. It would have been within the skill of the art to modify Steinbrink and use a litmus paper test strip to test the pH of the test solution to gain the above advantages and as optimization of a result effective variable.

It is notoriously well known in the art to provide an indicator or reactant in a dry state in the form of a tablet to gain the advantages of less weight for shipping, easier handling of the indicator or reagent in the form of a tablet and a longer shelf life. It would have been within the skill of the art to modify Steinbrink and provide the indicator or reactant in the form of a dry, tablet to gain the above advantages and as optimization of a result effective variable.

It is well known in the art to provide multiple chambers in a device so that plural samples and/or test can be conducted simultaneously which will shorten the time required for analysis. It would have been within the skill of the art to further modify

Art Unit: 1797

Steinbrink and provide at least two reaction chambers and/or two indicator chambers to gain the above advantages and as optimization of a result effective variable.

Response to Arguments

1. Applicant's arguments filed 5/18/09 and 9/23/09 have been fully considered but they are not persuasive.
2. Upon further consideration of the 5/18/09 and 9/23/09 amendments, the Office agrees the rejections over 35 USC 102 have been overcome, but believes a new 35 USC 103 rejection is appropriate.
3. The Office agrees with Applicant's characterization of Steinbrink as teaching the indicator chamber within the reaction chamber and that the claims are no longer anticipated under 35 USC 102(b). However, upon further consideration and in light of In re Larson above, the Office is taking the new position that substitution of an integral construction (e.g. Steinbrink) for the same elements arranged "externally" from each other would have been "merely a matter of obvious engineering choice."
4. The Office maintains the rejections of record are proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYLE A. ALEXANDER whose telephone number is (571)272-1254. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797